MAY 10 2010

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K092349

To establish substantial equivalence to the predicate, the Clearview® Exact II Influenza A & B Test was compared to the BinaxNOW® Influenza A & B Test (510(k) # K062109).

SUBMITTER
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DATE PREPARED
May 7, 2010

TRADE NAME
Clearview® Exact II Influenza A & B Test

COMMON NAME
Not applicable

CLASSIFICATION NAME
Antigen, Cf (including Cf Control), Influenza Virus A, B, C (per 21 CFR 866.3330)

PREDICATE DEVICE
BinaxNOW® Influenza A & B Test, K062109

DEVICE DESCRIPTION
The Clearview® Exact II Influenza A & B Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in respiratory swab specimens. These antibodies and a control protein are immobilized onto a membrane support as three distinct lines and are combined with other reagents/pads to construct a Test Strip.

Nasal swab samples are added to a Coated Reaction Tube to which an extraction reagent has been added. A Clearview Exact II Influenza A & B Test Strip is then placed in the Coated Reaction Tube holding the extracted liquid sample. Test results are interpreted at 10 minutes based on the presence or absence of pink-to-purple colored Sample Lines. The yellow Control Line tums blue in a valid test.

INTENDED USE

The Clearview® Exact II Influenza A & B Test is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasal swab specimens collected from symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

TECHNOLOGICAL CHARACTERISTICS

The Clearview® Exact II Influenza A & B Test and the predicate, the BinaxNOW® Influenza A & B Test, both use lateral flow immunochromatographic technology. Both tests are rapid immunoassays that employ specific antibodies immobilized onto solid phases to capture and visualize influenza nucleoprotein antigens.

PERFORMANCE SUMMARY

CLINICAL STUDY

Clearview® Exact II Influenza A & B Test Performance vs. Viral Culture – Prospective Study

The clinical performance of the Clearview® Exact II Influenza A & B Test was established in a multi-center, prospective, clinical study conducted at seven U.S. trial sites during the 2008-2009 respiratory season.

A total of 486 prospective specimens, collected from children (less than 18 years of age) and adults (18 years or older), were evaluated in the Clearview® Exact II Influenza A & B Test and compared to viral culture. Evaluated specimens were nasal swabs collected from patients presenting with influenza-like symptoms. Forty-four percent (44%) of the population tested was < 5 years of age, 31% was 5 - < 18 years of age, and 25% was ≥ 18 years. A/H3 and A/H1 were the predominant influenza A subtypes observed during this time.

Clearview® Exact II Influenza A & B Test performance versus viral culture, including 95% confidence intervals, is detailed below.

Clearview® Exact II Influenza A & B Test Performance vs. Culture

Influenza Type A

	Culture +	Culture -	
Clearview +	45	26	71
Clearview -	3	412	415
	48	438	486

Sensitivity: 45/48 = 94% (95% CI: 83–98%)
Specificity: 412/438 = 94% (95% CI: 91-96%)
PPV: 45/71 = 63% (95% CI: 52-74%)
NPV: 412/415 = 99% (95% CI: 98-100%)

Influenza Type B

	Culture +	Culture -	
Clearview +	68	13	81
Clearview -	19*	386	405
	87	399	486

Sensitivity: 68/87 = 78% (95% CI: 68-86%)
Specificity: 386/399 = 97% (95% CI: 95-98%)
PPV: 68/81 = 84% (95% CI = 74-90%)
NPV: 386/405 = 95% (95% CI = 93-97%)

* The nineteen samples that tested positive on culture for influenza B, but were negative on the Clearview® Exact II Test, were also tested on an investigational RT-PCR assay. Ten (10) of these samples were negative for influenza B by PCR.

ANALYTICAL STUDIES

ANALYTICAL SENSITIVITY

The Clearview® Exact II Test limit of detection (LOD or C_{95}), defined as the concentration of influenza virus that produces positive Clearview® Exact II Test results approximately 95% of the time, was identified by evaluating different concentrations of 2 subtypes of live influenza A and 2 strains of live influenza B in the Clearview® Exact II Test. Multiple operators tested each concentration of the four influenza strains multiple times. The concentrations identified as the LOD (C_{95}) levels for each strain tested are listed below.

Influenza Strain	Concentration ($TCID_{50}$/ml)	# Detected per Total Tests	% Detected
Influenza A/HongKong/8/68	2.37×10^4	64/66	97%
Influenza A/PuertoRico/8/34	3.16×10^5	37/42	88%
Influenza B/Malaysia/2506/2004	3.00×10^6	19/20	95%
Influenza B/Lee/40	4.20×10^5	19/20	95%

ANALYTICAL REACTIVITY TESTING

The influenza A and B strains listed tested positive in the Clearview® Exact II Influenza A & B Test at the concentrations specified. Although the specific influenza strains causing infection in humans can vary year to year, all contain the conserved nucleoproteins targeted by the Clearview® Exact II test.[1] Performance characteristics of the Clearview® Exact II Influenza A & B Test for detecting influenza A virus from human specimens was established when H1 and H3 subtypes were prevalent. Performance characteristics of the test when other influenza A virus subtypes are emerging as human pathogens have not been established.

Influenza Strain	Concentration
Flu A/Port Chalmers/1/73 (H3N2)	5.6×10^5 $TCID_{50}$/ml
Flu A/WS/33 (H1N1)	5.0×10^4 $TCID_{50}$/ml
Flu A/Aichi/2/68 (H3N2)	3.0×10^4 $TCID_{50}$/ml
Flu A/Malaya/302/54 (H1N1)	6.0×10^5 $TCID_{50}$/ml
Flu A/New Jersey/8/76 (H1N1)	2.8×10^5 $TCID_{50}$/ml
Flu A/Denver/1/57 (H1N1)	8.9×10^3 $TCID_{50}$/ml

Flu A/Victoria/3/75 (H3N2)	1.8×10^4 $TCID_{50}$/ml
Flu A/Solomon Islands/3/2006 (H1N1)	1.5×10^5 $TCID_{50}$/ml
Flu A/Brisbane/10/07 (H3N2)	2.5×10^6 EIU_{50}/ml
Flu A/PuertoRico/8/34 (H1N1)	5.6×10^5 $TCID_{50}$/ml
Flu A/Wisconsin/67/2005 (H3N2)	1.3×10^5 $TCID_{50}$/ml
Flu A/Hong Kong/8/68 (H3N2)	7.9×10^3 $TCID_{50}$/ml
Flu A/California/04/2009 (H1N1)	1.4×10^5 $TCID_{50}$/ml
Flu B/Florida/02/2006	1.4×10^4 $TCID_{50}$/ml
Flu B/Florida/04/2006	7.1×10^4 $TCID_{50}$/ml
Flu B/Florida/07/04	8.5×10^4 $TCID_{50}$/ml
Flu B/Malaysia/2506/04	1.5×10^6 $TCID_{50}$/ml
Flu B/Panama/45/90	1.7×10^4 $TCID_{50}$/ml
Flu B/R75	5.0×10^5 $TCID_{50}$/ml
Flu B/Russia/69	2.2×10^6 $TCID_{50}$/ml
Flu B/Taiwan/2/62	1.0×10^5 $TCID_{50}$/ml
Flu B/Mass/3/66	1.5×10^5 $TCID_{50}$/ml
Flu B/Lee/40	1.8×10^5 $TCID_{50}$/ml

Although this test has been shown to detect the Flu A/California/04/2009 (H1N1) virus cultured from a positive human specimen, the performance characteristics of this device with human specimens infected with the 2009 H1N1 influenza virus have not been established. The Clearview® Exact II Influenza A & B test can distinguish between influenza A and B viruses, but it does not differentiate seasonal influenza A virus from the novel influenza A (2009 H1N1) virus, and the test's ability to detect human infection with the novel influenza A 2009 H1N1 virus in clinical specimens is unknown.

ANALYTICAL SPECIFICITY (CROSS-REACTIVITY)

To determine the analytical specificity of the Clearview® Exact II Influenza A & B Test, 54 commensal and pathogenic microorganisms (38 bacteria, 15 viruses and 1 yeast) that may be present in the nasal cavity or nasopharynx were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^8 to 10^{10} cells/ml, CFU/ml or IFU/ml (bacteria), 10^5 to 10^8 $TCID_{50}$/ml or $CEID_{50}$/ml (viruses), and 10^9 cells/ml (yeast).

Bacteria	**Viruses**	**Yeast**
Acinetobacter calcoaceticus	Adenovirus type 1	*Candida albicans*
Bacteroides fragilis	Adenovirus type 7	
Bordetella pertussis	Coronavirus OC43	
Chlamydia pneumoniae	Coronavirus 229E	
Corynebacterium diphtheria	Coxsackievirus B4	
Enterococcus faecalis	Cytomegalovirus (CMV) (Herpes V)	
Escherichia coli	Epstein Barr Virus	
Gardnerella vaginalis	Human metapneumovirus	
Haemophilus influenzae	Measles (Edmonston)	
Klebsiella pneumoniae	Mumps (Enders)	
Lactobacillus casei	Parainfluenza 1	
Lactobacillus plantarum	Parainfluenza 2	
Legionella pneumophila	Parainfluenza 3	
Listeria monocytogenes	Respiratory Syncytial Virus type B	
Moraxella catarrhalis	Rhinovirus type 1A	
Mycobacterium avium		

Mycobacterium intracellulare
Mycobacterium tuberculosis
Mycoplasma pneumoniae
Neisseria gonorrhoeae
Neisseria meningitidis
Neisseria sicca
Neisseria subflava
Proteus vulgaris
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Staphylococcus aureus (Cowan protein A producing strain)
Staphylococcus epidermidis
Streptococcus, Group A
Streptococcus, Group B
Streptococcus, Group C
Streptococcus, Group F
Streptococcus, Group G
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus salivaris
Streptococcus sanguis

INTERFERING SUBSTANCES

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated in the Clearview® Exact II Influenza A & B Test at the concentrations listed below and were found not to affect test performance. Whole blood (1%) did not interfere with the interpretation of negative Clearview® Exact II Test results, but did interfere with the interpretation of influenza A LOD (C_{95}) positive samples. Therefore, visibly bloody samples may not be appropriate for use in this test.

Substance	Concentration
3 OTC nasal sprays	10%
3 OTC mouthwashes	10%
3 OTC throat drops	10%
4-acetamidophenol	10 mg/ml
Acetylsalicylic acid	20 mg/ml
Albuterol	20 mg/ml
Chlorpheniramine	5 mg/ml
Dexamethasone	5 mg/ml
Dextromethorphan	10 mg/ml
Diphenhydramine	5 mg/ml
Doxylamine succinate	1 mg/ml
Flunisolide	3 mg/ml
Guaiacol glycerol ether	20 mg/ml
Mucin	1%
Mupirocin	250 µg/ml
Oxymetazoline	10 mg/ml
Phenylephrine	10 mg/ml
Phenylpropanolamine	20 mg/ml

Rebetol® (Ribavirin)	500 ng/ml
Relenza® (Zanamivir)	20 mg/ml
Rimantadine	500 ng/ml
Tamiflu® (Oseltamivir)	100 mg/ml
Tobramycin	40 mg/ml
Triamcinolone	14 mg/ml

REPRODUCIBILITY

A reproducibility study of the Clearview® Exact II Influenza A & B Test was conducted by operators from 3 sites using panels of blind coded specimens containing negative, high negative (below the limit of detection), low positive (at the limit of detection), and moderate positive (above the limit of detection) influenza A and B viral samples. Participants tested each sample multiple times on 5 different days. The detection rates for the influenza A moderate positive, low positive, and high negative samples were 99.2% (119/120), 94.2 % (113/120) and 9.2% (11/120), respectfully. The detection rates for the influenza B moderate positive, low positive, and high negative samples were 99.2% (119/120), 96.7 % (116/120) and 7.5 % (9/120), respectfully. All of the negative samples (118) generated negative test results.

Signed Angela Drysdale Date 5/7/2010

Angela Drysdale
Director, Clinical Affairs
Binax, Inc., d/b/a Inverness Medical

[1] Dowdle, W.R, Kendal, A.P., and Noble, G.R. 1980. Influenza Virus. p 836-884. Manual of Clinical Microbiology, 3rd edition, In Lennette, et. Al (ed.). American Society for Microbiology, Washington, D.C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Ms. Anne Jepson
Manager, Clinical Affairs
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Inverness Medical Inc.
10 Southgate Road
Scarborough, ME 04074

MAY 10 2010

Re: k092349
Trade/Device Name: Binax Clearview® Exact II Influenza A &B Test.
Regulation Number: 21 CFR 866.3300
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: April 30, 2010
Received: May 3, 2010

Dear Ms. Jepson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092349

Device Name: Clearview® Exact II Influenza A & B Test

Indications For Use:

The Clearview® Exact II Influenza A & B Test is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasal swab specimens collected from symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – (CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092349